

REMARKS

All independent claims have been amended to improve the description of how the flap may be pressed towards the seal surface. In addition, claims 65 and 66 have been amended to specify that the single flexible flap has only one free portion.

Claims 69-70 have been added to this application. These claims require that the valve cover have a means for preventing the free end of the flexible flap from adhering to the interior of the valve cover's ceiling when moisture is present on the ceiling or on the flexible flap. The valve claim 69, thus, enables the flap to open and close without being hampered by moisture buildup. The structure of this valve is neither taught nor suggested in the prior art.

Examiner is Examining the Wrong Application:

Claims 33-36, 38-62, and 64-70 are now pending in this application.

In the most recent Office Action, the Examiner renumbered claims 67 and 68 as 57 and 58, respectively. Applicants submit that this change has been incorrectly made. Attached to this Amendment is a copy of a Preliminary Amendment that was filed on October 3, 2000, as well as a copy of the Amendment that was filed on October 5, 2001. As the Examiner will note, the Preliminary Amendment included claims 33 to 64, and the October 5, 2001 Amendment added claims 65 and 66. Thus, applicants did indeed properly number newly-added claims 67 and 68 in the Amendment that was filed on April 2, 2002. As indicated in the Amendment that was filed on April 2, 2002, applicants believe that the Examiner is referring to the wrong application in prosecuting this case. Applicants direct the Examiner's attention to page 3 of that Office Action. Please also note that the docket number assigned to this case is not correct. This is now the third consecutive Office Action that has been mailed, directed to the wrong case. **Please correct this error before issuing any further Office Actions.**

Double Patenting Rejection:

The claims have been rejected for double patenting over a number of copending applications. Applicants' invention includes a number of limitations that are not claimed in these copending cases. For example, in one embodiment the present invention requires a valve cover that is disposed over the valve seat and that comprises: (i) an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface

during an exhalation; (ii) a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end; and (iii) cross members that are disposed within the opening of the valve cover.

As the Examiner is aware, a double patenting rejection can only be sustained if the applicant is claiming the same invention that has been claimed in patent or an allowed patent application or if the applicant is claiming an invention that would have been obvious in view of an invention that is being claimed in such a document. In making the present double patenting rejection, the Examiner has not indicated whether the double patenting rejection is made under 35 USC § 101 or made under the judicially-created doctrine of obviousness type double patenting. Because none of the claims that are presented in this case are identical to the claims in any of applicants' copending applications or issued patents, applicants will assume, in making the following argument, that the claims have been rejected based on obviousness-type double patenting.

A double patenting rejection cannot be sustained for obviousness-type double patenting when no evidence has been presented to demonstrate that applicants' claimed invention is obvious over an invention claimed in any issued patent or allowed patent application. As the Examiner is also aware, obviousness-type double patenting is a judge-made doctrine that prevents an extension of the patent right beyond the statutory time limit. This type of rejection can only be sustained when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly-owned patent.¹ The purpose of the doctrine is to prevent an unjustified patent term extension by allowing a second patent to issue what claims an obviousness variant of the already-patented invention.² Generally, a "one-way" test has been applied to determine whether an obviousness-type double patenting rejection can be sustained. Under this test, the Examiner is supposed to ask whether the application claims are obvious over the patent claims.³ If the application claims are patentably distinct from the claims in the issued patent, then the double patenting rejection is not proper and must be withdrawn. If, however, the application is not patentably distinct, then the applicant can file a Terminal Disclaimer to eliminate the issue with respect to double patenting.⁴

¹ *In re Bratt*, 19 USPQ2d 1289, 1291-92 (Fed. Cir. 1991).

² *In re Goodman*, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993).

³ *In re Berg*, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998).

⁴ *In re Berg*, 46 USPQ2d at 1229.

It is incumbent upon the United States Patent and Trademark Office to clearly explain the reasons behind its rejection of a claim.⁵ Besides not furnishing applicants with the statutory basis for this rejection, the Examiner also has yet to identify any claim in any of applicants' patents (or any allowed copending application), which suggests the valve cover recited in the present claims. Until the Examiner can show where this feature, or an exhalation valve that is obviously similar, is also being patented by applicants, the obviousness-type double patenting rejection cannot be properly sustained. Presently, the Examiner has only cited all the claims that are in applicants' copending applications. In the absence of evidence demonstrating how the subject matter claimed in this application would have been obvious over the subject matter claimed in those copending cases, the double patenting rejection is not proper.

In any event, the Examiner has not allowed any claims in any of applicants' copending applications. Until such claims have been allowed and those claims have issued, the double patenting rejection is premature. You cannot terminally disclaim subject matter over a patent application that may never issue as a patent. Thus, any double patenting rejection can only be made provisionally. In this regard, the Examiner's attention is directed to MPEP § 804 I.B., 800-19 (August 2001).

"Claims 33-54, and 56-58" (sic) have been rejected under 35 USC § 103(a) as being unpatentable over UK Patent Application GB 2,072,516A to Simpson in view of U.S. Patent 3,191,618 to McKim, U.S. Patent 4,934,362 to Braun, and U.S. Patent 812,706 to Warbasse. Applicants' invention would not have been obvious to a person of ordinary skill in view of the teachings in these four documents for the following reasons.

Firstly, the subject matter of applicants' invention is structurally and functionally dissimilar to the subject matter described in Simpson. Applicants' invention requires a *flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when no external forces from the movement of fluid are exerted upon the flap*. Applicants' invention further requires a *valve cover that is disposed over the valve seat and that comprises: (i) an opening that is*

⁵ See, e.g., *In re Mindick*, 152 USPQ 566, 567 (CCPA 1967) ("As a general rule, we think examiners and the board have an obligation to state with precision the statutory basis for a rejection, unless the basis is otherwise clear from the terms used."); see also *In re Herrick*, 145 USPQ 400, 402 (CCPA 1965) ("Patent Office tribunals need to sufficiently explain the reasons for the rejection to permit a proper determination of the outstanding issue"); *In re Chilowsky*, 108 USPQ 321, 326 (CCPA 1956).

disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation; (ii) a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end; and (iii) cross members that are disposed within the opening of the valve cover. Simpson shows a flap-retaining surface and seal surface that are in direct alignment with each other. When closed, the Simpson flap would remain flat in planar alignment with its flap-retaining surface and seal surface. It would not be *pressed* against the seal surface when a wearer of the mask is neither inhaling or exhaling. An expert in the field of respirators and respirator components, David M. Castiglione, has provided evidence that establishes that the valve 13 shown in Figure 2 of the '516 U.K. Patent Application (Simpson) does not have its flap 15 *pressed* against the seal surface in an abutting relationship with it when a wearer would be neither inhaling nor exhaling. Castiglione states in paragraph 9 of his February 2, 2001 Affidavit (Exhibit A) that "there is nothing that can be discerned from Figure 2 [of Simpson] or from the [Simpson] specification that would indicate that the flap is pressed towards the seal surface in its neutral position." Another expert in the field of exhalation valves, John Bowers, (the inventor named in U.S. Patent 5,687,767) stated the following with respect to Simpson in paragraph 15 of his Declaration dated December 10, 2001 (Exhibit B):

My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

Given the aligned relationship between the flap retaining surface and the seal surface, there is no force exerted upon the flap that would bias the flap against the seal surface. The flap 15 can only reside in mere contact with the seal surface in the closed position. Simpson therefore places the exhalation valve 12 on the top portion 1 of its pouch-shaped mask (see Fig. 1 of Simpson) so that gravity can hold the valve shut when the wearer is neither inhaling nor exhaling. Gravity, however, does not constitute positioning the flap on the valve seat such that the flap is pressed towards the

seal surface in an abutting relationship with it. In addition, Simpson does not teach or suggest the use of the valve cover of the present invention.

Secondly, the secondary reference, U.S. Patent 3,191,618 to McKim, cannot be applied as a reference against applicants' invention because the McKim patent does not reside in an analogous art. As the Examiner is aware, a reference cannot be considered sufficiently analogous and thus relevant for determining obviousness unless it is either (1) within the field of the inventor's endeavor, or (2) is reasonably pertinent to the particular problem that confronted the inventor.⁶ Applicants' invention resides in the field of filtering face masks that use exhalation valves. McKim does not reside within this field of endeavor: it resides in the field of gasoline engines that use reed valves.

McKim shows a curved seat reed valve that is designed for use in a 2-cycle engine, which would turn at speeds as high as 10,000 or 12,000 revolutions per minute. In contrast, applicants' invention pertains to a filtering face mask that employs an exhalation valve, which opens in response to a wearer's breathing. Castiglione explained in his November 15, 1999 Affidavit (Exhibit C) why McKim does not reside in the field of endeavor of applicants' invention:

The field of endeavor for a filtering face mask is very different from the field of endeavor of a curved seat reed valve that is used in a high-speed engine. Persons of ordinary skill in the field of designing filtering face masks do not consult documents that describe valves for gasoline engines in developing respiratory products. Exhalation valves for respirators operate under very different conditions from valves that are used in gasoline engines and require extraordinary different design parameters.

Another investigator who works in the filtering face mask field, John L. Bowers, explains why McKim is not in the field of endeavor of a person of ordinary skill in the art designing exhalation valves:

My review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which could turn at speeds as possibly as high as 10,000 or 12,000 revolutions per minute (rpm). The reed valve described in McKim is indicated to be particularly suited for a high speed operation where opening and closing forces are large. McKim states these forces can cause the valve to bounce (an apparent elastic recoil from impact). The stated goals in McKim are full and rapid opening, quick and complete closing, and eliminating float and bounce.

⁶ *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

VERSION WITH MARKINGS TO SHOW CHANGES MADE

33. (amended) A filtering face mask that comprises:

- (a) a mask body that is adapted to fit over the nose and mouth of a wearer; and
- (b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

- (1) a valve seat that comprises:

- (i) a seal surface; and

- (ii) an orifice that is circumscribed by the seal surface.

- (2) a single flexible flap that has a fixed portion and a free portion and first and second opposing ends, the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during an exhalation, and the second end being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when [a fluid is not passing through the orifice] no external forces from the movement of fluid are exerted upon the flap; and

- (3) a valve cover that is disposed over the valve seat and that comprises:

- (i) an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation;

- (ii) a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end; and

- (iii) cross members that are disposed within the opening of the valve cover.

65. (amended) A filtering face mask that comprises:

- (a) a mask body that is adapted to fit over the nose and mouth of a wearer; and
- (b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

- (1) a valve seat that comprises:
 - (i) a seal surface; and
 - (ii) an orifice that is surrounded by the seal surface.
- (2) a single flexible flap that is supported by the valve seat and that has a stationary portion and [a] only one free portion and a peripheral edge that includes stationary and free segments, the stationary segment of the single flexible flap's peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment of the flap's peripheral edge being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the filtering face mask is worn on a person, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when [a fluid is not passing through the orifice] no external forces from the movement of fluid are exerted upon the flap; and
- (3) a valve cover that is disposed over the valve seat and that comprises:
 - (i) an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation;
 - (ii) a fluid impermeable ceiling that is spaced further from the valve seat above the free segment of the flap's peripheral edge than above the stationary segment of the flap's peripheral edge; and
 - (iii) cross members that are disposed within the opening of the valve cover.

66. (amended) A filtering face mask that comprises:

- (a) a mask body that is adapted to fit over the nose and mouth of a wearer; and
- (b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

- (1) a valve seat that comprises:
 - (i) a seal surface; and
 - (ii) an orifice that is circumscribed by the seal surface.

(2) a single flexible flap that is supported by the valve seat and that has a stationary portion and [a] only one free portion and a peripheral edge that includes stationary and free segments, the stationary segment of the single flexible flap's peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment of the flap's peripheral edge being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the filtering face mask is worn on a person, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when [a fluid is not passing through the orifice] no external forces from the movement of fluid are exerted upon the flap; and

(3) a valve cover that is disposed over the valve seat and that comprises:

(i) an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation;

(ii) a fluid impermeable ceiling that is higher above the free segment of the flap's peripheral edge than above the stationary segment of the flap's peripheral edge; and

(iii) cross members that are disposed within the opening of the valve cover;

wherein during an exhalation, the free portion of the flexible flap lifts from the seal surface and moves towards the fluid impermeable ceiling so that exhaled air can exit through the opening in the valve cover.

67. (amended) A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) an orifice; and

(ii) a seal surface that surrounds the orifice when the valve seat is viewed from the front;

(2) a single flexible flap that is supported by the valve seat and that has a stationary portion and a free portion and a peripheral edge that includes stationary and free segments, the stationary segment of the single flexible flap's peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment of the flap's peripheral edge being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the filtering face mask is worn on a person, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when [a fluid is not passing through the orifice] no external forces from the movement of fluid are exerted upon the flap; and

(3) a valve cover that is disposed over the valve seat and that comprises:

(i) an opening that is disposed in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation; and

(ii) a fluid impermeable ceiling that is higher above the free segment of the flap's peripheral edge than above the stationary segment of the flap's peripheral edge;

wherein during an exhalation, the free portion of the flexible flap lifts from the seal surface and moves toward the fluid impermeable ceiling so that exhaled air can exit through the opening in the valve cover.